IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

RALPH ARNETT, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:10-cv-00114

MYLAN, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending before the court is the defendants' Partial Motion to Dismiss Complaint [Docket 9]. For the reasons explained below, the Motion is **GRANTED**.

I. Background

This is a products liability action. According to the Complaint, in 2008 Susan Arnett was prescribed the Mylan Fentanyl Transdermal System ("MFTS" or the "patch"), a patch that administers the pain drug fentanyl through the skin. Ms. Arnett was wearing the patch when she died on February 14, 2008. The medical examiner determined that her death was caused by fentanyl intoxication.

On February 3, 2010, Ms. Arnett's husband, Ralph Arnett, filed suit on behalf of her estate.[1] The Complaint asserts five state-law causes of action against the patch manufacturers. The plaintiff, an Oklahoma resident, has sued the defendants—Mylan, Inc., Mylan Pharmaceuticals, Inc., and

[1]Although Mr. Arnett and Mrs. Arnett's estate are listed as plaintiffs in this case, for ease of reference, I will refer to them as "Arnett" or "the plaintiff."

Mylan Technologies, Inc. (collectively, "Mylan" or the "defendants")—corporate residents of West Virginia, in West Virginia federal court. Federal courts sitting in diversity are obliged to apply the law of the forum state. *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938). As such, West Virginia choice-of-law principles apply. *Klaxon Co. v. Stentor Electric Mfg. Co.*, 313 U.S. 487, 496-97 (1941); *Pen Coal Corp. v. William H. McGee and Co., Inc.*, 903 F. Supp. 980, 983 (S.D. W. Va. 1995). West Virginia uses the *lex loci delicti* (place of the injury) test in tort actions. *Chemtall, Inc. v. Madden*, 607 S.E.2d 282 (W. Va. 2004) The place of the injury in this case was Oklahoma; Oklahoma law therefore applies.

The defendants filed the motion for partial dismissal, asking to dismiss the third claim of the Complaint. That count asserts a claim under the Oklahoma Consumer Protection Act. The defendants argue that the claim must be dismissed as a matter of law.

II. Standard

A motion to dismiss filed under Federal Rule of Civil Procedure 12(b)(6) tests the legal sufficiency of a complaint. *Giarratano v. Johnson*, 521 F.3d 298, 302 (4th Cir. 2008). To survive a Rule 12(b)(6) motion to dismiss, a plaintiff must allege enough facts "'to raise a right to relief above the speculative level' and must provide 'enough facts to state a claim to relief that is plausible on its face.'" *Robinson v. Am. Honda Motor Co., Inc.*, 551 F.3d 218, 222 (4th Cir. 2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

III. Discussion

Count Three of the Complaint asserts a claim under the Oklahoma Consumer Protection Act, 15 Okla. Code, Ch. 20 ("OCPA"). The OCPA provides consumers with a private cause of action against companies engaged in the business of marketing and distributing consumer products that

make a false representations or engage in deceptive trade practices. The plaintiff asserts that the defendants violated the OCPA by failing to disclose to consumers the risks associated with using the patch.

The OCPA contains an exception, however. It provides that "[n]othing in this Act shall apply to . . . [a]ctions or transactions regulated under laws administered by . . . any . . . regulatory body or officer acting under statutory authority of this state or the United States." 15 Okla. Stat. § 754(2). Claims encompassing such "actions and transactions" may not be pursued under that Act. *See, e.g., Estate of Hicks ex rel. Summers v. Urban East, Inc.*, 92 P.3d 88 (Okla. 2004) (holding that claim for nursing-home neglect was excluded by the OCPA because of existing state regulation of nursing homes). The plaintiffs' OCPA claim asserts that the defendants are "engaged in the business of marketing and distributing pharmaceutical drugs for sale to and use by consumers" and that they "committed an unfair or deceptive trade practice as defined in [the OCPA] by failing to disclose the information they had acquired regarding the serious risks involved with using the Patches." (Compl. ¶¶ 27, 28.) Whether the exception in section 754(2) forecloses the plaintiff's OCPA claim is the issue before the court.

The defendants argue that the OCPA claim must fail as a matter of law, because federal law heavily regulates the labeling of generic prescription drugs, and that the claim is excluded by section 754(2). The plaintiff maintains that for section 754(2) to apply, the alternative federal or state regulatory scheme must provide plaintiffs with an independent cause of action. Because the federal

law and regulations relied on by the defendants provides no indepedent remedy, the plaintiff argues, the section 754(2) exception does not apply.[2]

There is no decision from the Supreme Court of Oklahoma—or any Oklahoma court, for that matter—addressing this issue. One out-of-state federal court, however, has addressed this very question. In *Money v. Bristol-Myers Squibb Co.*, 2009 WL 5216987 (D.N.J. December 30, 2009), the Oklahoma plaintiff sued a pharmaceutical company for violations of the OCPA. The defendants argued that the OCPA claim had to be rejected simply because pharmaceuticals are regulated by the FDA—the same argument that Mylan makes in this case. The plaintiff argued that to determine whether section 754(2) applies, "a court must examine the purposes of the conflicting regulatory scheme and determine whether the conflicting regulatory scheme can properly address and remedy the dispute underlying a plaintiff's OCPA claim." *Money*, 2009 WL 5216987 at *6. Because the OCPA was broader in scope than the FDA's regulatory powers, and (as Arnett argues) because the FDCA offered no private right of action, the plaintiff maintained, section 754(2) could not apply.

The court rejected both parties' arguments. The court first rejected the plaintiff's argument, explaining that

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[2]The plaintiff also argues that the defendants' motion is foreclosed by the Supreme Court's decision in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009). That case held that the federal regulatory regime governing pharmaceuticals does not preempt state-law failure-to-warn claims against name brand manufacturers. In relying on *Levine*, the plaintiff seems to confuse federal preemption principles with issues of statutory interpretation.

Issues of federal preemption arise when a party seeks to invalidate a state law on the grounds that it conflicts, expressly or impliedly, with federal law. But preemption is not an issue in this case. The defendants have not asserted that the OCPA claim is preempted by federal law. Instead, the defendants argue that the OCPA, by its own terms, does not provide a cause of action for the plaintiff's claim. The OCPA itself has carved out an exception for any "action or transaction" that is regulated by state or federal law. The inquiry is whether the federal government regulates the marketing and distribution of generic prescription drugs, and whether that marketing and distribution constitutes a "transaction" under the OCPA. If so, then the claim is excluded and must be dismissed.

> while the purpose of the FDCA may indeed be similar to that of the OCPA, i.e. consumer protection, Plaintiff may not bring a private cause of action. Contrary to Plaintiff's suggestion, that fact is not a fait accompli to the inapplicability of § 754(2). Indeed, while an individual consumer remedy in the form of a private right of action may be unavailable under the federal regulatory scheme, that scheme exists to afford protection to consumers, which may indeed be sufficient remedy.

Id. But the court also rejected the defendant's argument:

> The fact that the FDA regulates the labeling and marketing of pharmaceuticals is not a fait accompli to the application of the exemption. While the FDA may indeed regulate the promotion and marketing of Plavix, the parties have failed to provide the Court with any factual information or legal analysis involving the regulatory scheme at issue. The issue for this Court's determination is whether the promotional materials that Plaintiff identifies as deceptive were nevertheless in compliance with FDA regulations governing those materials. If indeed Defendants were compliant, then the Court could find the statutory exemption applicable. If, however, Defendants' promotional materials were not authorized by the FDA's regulatory scheme in that they were either not in compliance or are not among the type of materials that the FDA monitors then the statutory exemption would be inapplicable. The Court rejects Defendants' assertion that the exemption is applicable merely because the promotion and marketing of prescription drugs are generally regulated by the FDA.

Id. The court denied the pharmaceutical defendant's effort to dismiss the plaintiff's OCPA claim based on section 754(2), because the issue had not been adequately briefed before the court. But the court nevertheless dismissed the OCPA claim based on insufficient pleading.

While I agree with the *Money* court's reasoning regarding the plaintiff's contention, I cannot agree with its interpretation of section 754(2). In answering questions of statutory interpretation, one must begin with the text of the statute. The OCPA excludes both "actions" and "transactions" that are regulated by state or federal law. The statute is not, as Arnett advocates, limited to statutory regimes that provide plaintiffs with a cause of action.

Although the term "actions" certainly contemplates this, the inclusion of the additional term "transactions" suggests something broader. Were the court to adopt Arnett's reading of the

statute—that section 754(2) only excludes a claim when another statute affords its own cause of action—the term "transactions" would be rendered superfluous. A transaction is "any activity involving two or more persons." *Black's Law Dictionary* 1503 (7th ed. 1999). Clearly, the marketing, distribution, and sale of pharmaceuticals is a "transaction." And this transaction is certainly "regulated by a regulatory body . . . acting under the statutory authority . . . of the United States." 15 Okla. Stat. § 754(2)

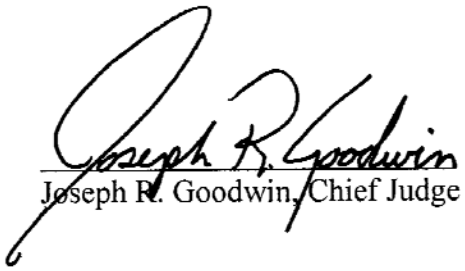
Section 754(2) of the OCPA states that claims arising from transactions regulated by federal law cannot be brought under the OCPA. The distribution and sale of pharmaceutical drug products is a comprehensively regulated activity under the federal Food, Drug, and Cosmetic Act ("FDCA"). *See* 21 U.S.C. §§ 321, *et seq*; *Levine*, 129 S. Ct. at 1199 ("Congress enacted the FDCA to bolster consumer protection against harmful products."). A prescription pharmaceutical product may not be marketed in the United States unless and until the Food and Drug Administration ("FDA") has approved the sale of that product pursuant to the FDCA.

Contrary to the *Money* court's analysis, the simple language of section 754(2) focuses solely on whether there is regulation, not whether there is compliance. The Act's clear language rebuffs the plaintiffs' attempt to interject ambiguity into section 754(2). Clearly, the defendants' marketing and distribution of the patch constitutes a transaction that is regulated by federal law. Therefore, the plaintiffs' OCPA claim must fail in light of this statutory exception.

IV. Conclusion

The defendants' Motion [Docket 9] is **GRANTED**. The plaintiffs' OCPA claim (the third cause of action in the Complaint) is **DISMISSED**. The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 20, 2010



Joseph R. Goodwin, Chief Judge